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a transport device adapted to transport lancets  
an opening into which the lancing device can be inserted to remove an  
individual lancet from the lancet magazine, and  
each of the plurality of lancets comprising a pin configured to prevent the  
lancet from being displaced in the lancet magazine when the lancing device is inserted.

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#### REMARKS

##### Introductory Comments

Prior to this Amendment, claims 22-32 and 43-51 are pending in the above-referenced application. In the October 24, 2001 Office Action, Examiner Ngo allowed claims 26, 31, and 32, rejected claims 22-25, 27-30, 43, and 46-49, and objected to claims 44, 45, 50, and 51.

Applicants acknowledge with appreciation the allowance of claims 26, 31, and 32, and the Examiner's indication that claims 44, 45, 50 and 51 would be allowable if rewritten in independent form. (Office Action, page 4). By this Amendment, Applicants have amended claims 22, 44, 45, 47, 50, and 51. Claim 22 is amended solely to further clarify the claimed invention, and claims 44, 45, 47, 50, and 51 are amended solely to place them in proper form for allowance. Thus, claims 22-32 and 43-51 remain pending in the above-referenced application.

##### In The Drawings

The Examiner objected to the drawings under 37 C.F.R. 1.83(a) as failing to show the conical shape of the opening as claimed in claim 49. (Office Action, paragraph 1).

Fig. 4B shows opening 9 having a circular shape. The written description explains that "the opening can have a conical or funnel shape so that it is larger towards the outside than is necessary to receive the tip of the lancing device." (Specification, page 10, first full paragraph, lines 11-14). Applicants submit that Fig. 4B, in combination with the written description, is sufficient for a proper understanding of the invention of claim 49 in accordance with 37 C.F.R. 1.83(a).

Accordingly, Applicants respectfully request that the objection to the drawings be withdrawn.

##### Claim Objections

Applicants acknowledge with appreciation the Examiner's indication that previously misnumbered claims 33-41 have been renumbered and are now claims 43-51. (Office Action, paragraph 2). Claims 44, 45, 50, and 51 are amended in accordance with paragraph 8 of the Office Action, and not to overcome any prior art. Applicants respectfully request that claims 44, 45, 50, and 51 be allowed.

Claim Rejections Under 35 U.S.C. § 112, first paragraph

The Examiner rejected claim 49 under 35 U.S.C. § 112, first paragraph, incorrectly asserting that “the opening has a conical shape” is not supported in the specification.” (Office Action, paragraph 4). Applicants respectfully direct the Examiner to page 10, 7 lines from the bottom of the page, wherein Applicants state that “to facilitate the insertion of the lancing device into the opening, the opening can have a conical or funnel shape.” Accordingly Applicants request that the rejection of claim 49 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claim Rejections Under 35 U.S.C. § 102(b)

Claims 22-25, 27-30, 43, and 46-48 were rejected under 35 U.S.C. § 102(b) as being anticipated by Douglas, U.S. Patent No. 3,696,915.

“To anticipate a claim under 35 U.S.C. §§ 102(a), (b), or (e), the cited reference must contain each and every element as set forth in the claim.” Manual of Patent Examining Procedure (Aug. 2001) (“MPEP”) § 2131 at 2100-69. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Id.* (citing Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987)). The words of a claim “must be read as they would be interpreted by those of ordinary skill in the art.” MPEP § 2111.02 at 2100-48 (citing In re Sneed, 710 F.2d 1544 (Fed. Cir. 1983)).

Regarding claims 22-23 and 25, the Examiner has improperly equated Douglas’s razor 16 to Applicants’ claimed lancing device, Douglas’s razor blade magazine 10 to Applicants’ lancet magazine, and Douglas’s razor blades 12 to Applicants’ lancets.

Applicants have amended claim 22 to further clarify that the lancing device is suitable “for guiding the lancet to pierce the skin of a person to a defined puncture depth.” This

amendment is supported, for example, at page 5, first paragraph, of the specification: “the lancet that is held, guided and driven by the lancing device pierces the skin of this person to a defined puncture depth and thus forms a tiny wound.”

Further, at page 2, first full paragraph of the specification, Applicants explain that “lancets and . . . lancing devices . . . enable a substantially pain-free and reproducible blood collection.” Thus, Applicants claimed lancet is used to cause small injuries.

In contrast, Douglas discloses that the blades 12 may “subject the user to a possible injury.” col. 1 line 44. Douglas’s blade dispenser is designed such that “accidental injury to the user . . . is eliminated.” col. 3 lines 35-38. Douglas therefore seeks to avoid the use of blades 12 to create a wound in a person, presumably because such injury could be severe. Nothing in Douglas teaches or suggests the use of razor 16 and blades 12 to collect fluid from a person, particularly by piercing the skin to a defined puncture depth. One of ordinary skill in the art would immediately understand that Douglas’s razor 16 and blades 12 are designed to remove body hair and not to collect body fluid. Further, one of ordinary skill would readily appreciate that Douglas’s razor is not designed to create a tiny wound, particularly of “defined puncture depth” as recited in claim 22.

For at least these reasons, Douglas’s razor 16, blades 12, and blade magazine 10 do not read on Applicants’ claims, and the Examine’s rejection under 35 U.S.C. § 102(b) is improper. Applicants respectfully request that such rejections be withdrawn.

Regarding claims 24 and 27-30, the Examiner contends that Douglas discloses a “lancet magazine” having a flat angular shape and a transport device driven by a spring mechanism. However, the Examiner does not provide any citations to Douglas to support his contention. Nonetheless, claims 24 and 27-30 depend from claim 22, which Applicants submit is allowable. Accordingly, Applicants respectfully request that the rejections of claims 24 and 27-30 also be withdrawn.

Regarding claims 43 and 46-48, the Examiner contends that it is “inherent that the blade including a tip, and the razor including a holding tongue and an ejector.”

“In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” MPEP § 2112 at 2100-52 (quoting Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added)).

The Examiner has failed to provide any basis in fact and/or reasoning to support his conclusion. Accordingly, the rejection of claims 43 and 46-48 is improper. Further, all of claims 43 and 46-48 depend from independent claim 22, which Applicants submit is allowable. For at least these reasons, Applicants respectfully request that the rejections of claims 43 and 46-48 be withdrawn.

Final Remarks

For at least the reasons stated, above, all of the pending claims 22-32 and 43-51 of the above-noted application are believed to be in condition for allowance. Applicants respectfully request that the Examiner so find and issue a Notice of Allowance in due course. The Examiner is asked to call Applicants’ attorney, Christine E. Mayewski Orich at 317-684-5414, or James A. Coles at 317-684-5251, to address any outstanding issues in order to expedite the prosecution of this application for all parties.

If necessary, Applicants request that this Amendment be considered a request for an extension of time for a time appropriate for the response to be timely filed. Applicants request that any required fees needed beyond those submitted with this Response be charged to the account of Bose McKinney & Evans, Deposit Account No. 02-3223.

Respectfully submitted,



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APPENDIX  
MARKED-UP VERSION OF CLAIMS

22. (Amended) A system that is suitable for collecting a body fluid from a region of the body of a person to be examined, the system comprising:

a lancing device which is suitable for holding a lancet and for guiding the lancet to pierce the skin of a person to a defined puncture depth, and

a lancet magazine for storing a plurality of lancets, the lancet magazine comprising

a transport device adapted to transport lancets and

an opening into which the lancing device can be inserted to remove an individual lancet from the lancet magazine.

✓ 44. (Amended) [The system of claim 33, further comprising] A system that is suitable for collecting a body fluid from a region of the body of a person to be examined, the system comprising:

a lancing device which is suitable for holding a lancet and

a lancet magazine for storing a plurality of lancets, the lancet magazine comprising

a transport device adapted to transport lancets and

an opening into which the lancing device can be inserted to remove an individual lancet from the lancet magazine, and

each of the plurality of lancets in the lancet magazine comprising a sterile tip and a protective sheath surrounding the sterile tip.

✓ 45. (Amended) The system of claim [34] 44, wherein the protective sheath is removed when the lancing device is inserted into the lancet magazine.

47. (Amended) The system of claim [36] 46, wherein the holding tongue includes a barb and an ejector.

50. (Amended) [The system of claim 22,] A system that is suitable for collecting a body fluid from a region of the body of a person to be examined, the system comprising:

a lancing device which is suitable for holding a lancet and  
a lancet magazine for storing a plurality of lancets, the lancet magazine  
comprising

a transport device adapted to transport lancets  
an opening into which the lancing device can be inserted to remove an  
individual lancet from the lancet magazine, and

[wherein] each of the plurality of lancets [includes] comprising a lancet body having opposed recesses configured to engage the lancing device.

51. (Amended) [The system of claim 22,] A system that is suitable for collecting a body fluid from a region of the body of a person to be examined, the system comprising:

a lancing device which is suitable for holding a lancet and  
a lancet magazine for storing a plurality of lancets, the lancet magazine  
comprising

a transport device adapted to transport lancets  
an opening into which the lancing device can be inserted to remove an  
individual lancet from the lancet magazine, and

[wherein] each of the plurality of lancets [includes] comprising a pin configured to prevent the lancet from being displaced in the lancet magazine when the lancing device is inserted.